

We claim:

1. A sustained/prolonged release pharmaceutical formulation comprising:
  - (a) a water soluble medicament and (b) a polymer mixture comprising a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent polyvinyl pyrrolidone of the total weight of said first component, combined with a second component comprising a cellulose ether polymer.
2. A pharmaceutical unit dosage form according to claim 1 wherein said first component is present in an amount ranging from about 20 weight percent to about 90 weight percent of the total formulation and said second component ranges from about 2 weight percent to about 60 weight percent of the total weight of the formulation.
3. The formulation according to claim 2 wherein said cellulose ether polymer is selected from the group consisting of methyl -, ethyl -, hydroxyethyl -, hydroxypropyl - or hydroxypropyl methyl - substituted polymers of Methocel A series; hydroxyethyl celluloses of METHOCEL E, F, J, or K series at various viscosity grades; different viscosity grades of hydroxy propyl cellulos of Klucel, or Methocel series; a low substituted grades of hydroxypropyl celluloses of the LH series, and ethyl celluloses of ETHOCEL P series, or a mixture of any of the foregoing ethers.
4. The formulation according to claim 3 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine, theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable

acid addition salt of metolopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone; a pharmaceutically acceptable acid addition salt of zolpidem; a pharmaceutically acceptable acid addition salt of sertraline; a pharmaceutically acceptable acid addition salt of labetalol; and a pharmaceutically acceptable acid addition salt of atenolol.

5. A pharmaceutical construct comprising:

- (a) a water soluble medicament;
- (b) a polymer mixture comprising (a') a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent polyvinyl pyrrolidone of the total weight of said first component; combined with (b') a second component comprising a cellulose ether polymer.

6. The pharmaceutical construct as defined in claim 5, wherein said first component is present in an amount ranging from about 20 weight percent to about 90 weight percent of the total formulation and said second component ranges from about 2 weight percent to about 60 weight percent of the total weight of the formulation

7. The pharmaceutical construct as defined in claim 6 wherein said cellulose ether is selected from the group consisting of methyl cellulose, hydroxy propyl cellulose, hydroxy propyl methyl cellulose METHOCEL A series, METHOCEL E series, METHOCEL F series, METHOCEL K series, Metoloses LH series, ETHOCEL P series, or a mixture of any of the foregoing cellulose ethers.

8. The pharmaceutical construct as defined in claim 7 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt

of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine, theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable acid addition salt of metoclopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone; a pharmaceutically acceptable acid addition salt of zolpidem; a pharmaceutically acceptable acid addition salt of sertraline; a pharmaceutically acceptable acid addition salt of labetalol; and a pharmaceutically acceptable acid addition salt of atenolol.

9. A process for the preparation of a sustained/prolonged release pharmaceutical unit dosage form comprising the steps of:

(a) fluidizing a water soluble medicament combined with a carrier, comprising a polymer mixture comprising a first component, comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of polyvinyl pyrrolidone of the total weight of said first component, combined with a second component comprising a cellulose ether polymer; to form a fluidized mixture;

- (b) direct blending the mixture to form a blended mixture;
- (c) granulating said blended mixture to form a granulated mixture; and
- (d) tableting said granulated mixture and/or blend to form a tablet.

10. The process according to claim 9 wherein said water soluble medicament is selected from the group consisting of a pharmaceutically acceptable addition salt of hydroxyzine, a pharmaceutically acceptable addition salt of metoprolol, niacin, caffeine,

theophylline, a pharmaceutically acceptable acid addition salt of diltiazem, a pharmaceutically acceptable acid addition salt of albuterol, a pharmaceutically acceptable acid addition salt of metformin, a pharmaceutically acceptable acid addition salt of metronidazole, a pharmaceutically acceptable acid addition salt of metoclopramide, a pharmaceutically acceptable acid addition salt of ranitidine, a pharmaceutically acceptable acid addition salt of captopril, a pharmaceutically acceptable acid addition salt of nefazodone; a pharmaceutically acceptable acid addition salt of zolpidem; a pharmaceutically acceptable acid addition salt of sertraline; a pharmaceutically acceptable acid addition salt of labetalol; a pharmaceutically acceptable acid addition salt of atenolol.

10 ~~11~~. A modulated release pharmaceutical construct which comprises a matrix of a water soluble medicament associated with a polymer mixture, where said mixture comprises a first component, comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of polyvinyl pyrrolidone of the total weight of said first component, combined with a second component comprising a cellulose ether polymer and a medicament associated with said matrix.

11 ~~12~~. A sustained release pharmaceutical composition comprising a construct comprising a water soluble medicament and a polymer mixture, comprising a first component comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of the total weight of said first component of polyvinyl pyrrolidone, combined with a second component comprising a cellulose ether polymer.

12 ~~13~~. A process for preparing a sustained/prolonged release pharmaceutical unit dosage form, which comprises:

(a) blending a water soluble medicament with a polymer mixture comprising a first component, comprising about 80 weight percent of polyvinyl acetate combined with about 20 weight percent of polyvinyl pyrrolidone of the total weight of said first component, combined with a second component, comprising a cellulose ether polymer, to form a mixture; and

(b) tableting said mixture

*Rule 1.126*  
*13* ~~14~~. The process as defined in claim ~~13~~ <sup>12</sup> wherein the tableting is conducted under direct compression.

*14* ~~15~~. The process as defined in claim ~~13~~ <sup>12</sup> wherein said polymer and drug are blended by means of wet granulation followed by dry blending.

*15* ~~16~~. The process as defined in claim ~~13~~ <sup>12</sup> wherein all materials are wetted prior to said blending and dried and milled after said blending.